5. 510(k) Summary

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AUG 16 2007

Submitter's name:	FertiPro N.V.
Address:	Industriepark Noord 32 Beernem West-Vlaanderen, Belgium 8730
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Name of contact person:	Grace Holland Regulatory Specialists, Inc 3722 Ave. Sausalito Irvine, CA 92606 Phone: 949-262-0411 Fax: 949-552-2821 Email: grace@regulatoryspecialists.com

Date the summary was prepared: August 13, 2007

Name of the device:	VitriFreeze
Trade or proprietary name:	VitriFreeze Media, Pre incubation, 1 and 2
Common or usual name:	Vitrification freezing media
Classification name:	Reproductive media

Name of the device:	VitriThaw
Trade or proprietary name:	VitriThaw Media 1, 2, 3, and 4
Common or usual name:	Vitrification thawing media
Classification name:	Reproductive media

The legally marketed devices to which we are claiming equivalence [807.92(a)(3)]:

Device	Ref#	Applicant	Decided
VITRIFICATION FREEZE KIT, VITRIFICATION THAW KIT	K060168	Irvine Scientific Sales	04/24/2006

Description of the devices:

The seven (7) media that comprise the two (2) VitriFreeze and VitriThaw media are all based upon a modified formulation of other media.

The three (3) freeze media in VitriFreeze are intended for use sequentially and are named Pre-incubation medium, VitriFreeze Medium 1 and VitriFreeze Medium 2. These media are used for preparation for and cryopreservation of human blastocysts. Pre-incubation medium is used to equilibrate the blastocysts. VitriFreeze, Medium 1 is used for the preparation to the vitrification. VitriFreeze, Medium 2 is the actual vitrification medium that is used during cryostorage.

The four (4) thawing media in VitriThaw are also for sequential use in the thawing and recovery of cryopreserved human blastocysts. VitriThaw media includes VitriThaw Medium 1, VitriThaw Medium 2, VitriThaw Medium 3, VitriThaw Medium 4

Indications:

VitriFreeze is intended for ultra-rapid freezing of human blastocysts for Assisted Reproductive Technology (A.R.T.) procedures.

VitriThaw is intended for the recovery of human blastocysts that have undergone ultra-rapid freezing using FertiPro's VitriFreeze, for Assisted Reproductive Technology (A. R.T.) procedures.

Summary of the technological characteristics of our device compared to the predicate device:

The predicates and these devices were compared in the following areas and found to have similar technological characteristics and to be equivalent.

Formula
Special controls
Packaging
Performance Testing

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG 16 2007

FertiPro N.V.
c/o Ms. Grace Holland
Regulatory Specialist
Regulatory Specialists, Inc.
3722 Ave. Sausalito
IRVINE CA 92606

Re: K070135
Trade Name: VitriFreeze Media and VitriThaw Media
Regulation Number: 21 CFR §884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: MQL
Dated: August 1, 2007
Received: August 2, 2007

Dear Ms. Holland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statements

Indications for Use

510(k) Number (if known): K070135

Device Name: VitriFreeze Media

VitriFreeze Media are intended for ultra-rapid freezing of human blastocysts for Assisted Reproductive Technology (A.R.T.) procedures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

J.W. Chang

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070135

Indications for Use

510(k) Number (if known): K070135

Device Name: VitriThaw Media

VitriThaw media are intended for the recovery of human blastocysts that have undergone ultra-rapid freezing for Assisted Reproductive Technology (A.R.T.) procedures.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
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